

Surgical Instrument Service & Sterilization

KD42659
510(k) Summary of Safety & Effectiveness

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:

MediSISS

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September 27, 2004

FEB 14 2005

Contact Person

Brandi James

Proprietary Name

MediSISS Reprocessed Non-electric GI Biopsy Forceps

Common Name

Reprocessed Cold GI Biopsy Forceps

Classification

Gastroenterology/Urology Forceps, Biopsy, Reprocessed, per 21 CFR 876.1075, Product Code: NON, Regulatory Class II.

Device Description and Technological Characteristics:

MediSISS Reprocessed Non-electric GI Biopsy Forceps are designed for endoscopic use to retrieve tissue samples for microscopic inspection. Forceps outer diameters range from 2.2mm to 2.5mm and working lengths vary from 160cm to 240cm. A syringe-like proximal handle opens and closes the distal instrument jaws, that are available in multiple design configurations such as Oval, Alligator, Smooth, or Fenestrated with and without a needle. The working length of the biopsy forceps is coated with a plastic sheath to decrease friction.

Predicate Device 510(k)s

Identification of legally marketed predicate device Original Equipment Manufacturer's 510(k)s:

Manufacturer	510(k) #
Bard	K912549
Esco Precision, Inc.	K900015
Olympus	K955065

Summary of Validation Data: MediSISS has validated its cleaning, sterilization, functional performance and packaging and distribution processes for Reprocessed Non-Electric GI Biopsy Forceps. Successful validation, and routine tests monitor the safety and effectiveness of our product post sterilization. We have demonstrated with a high degree of assurance that MediSISS Reprocessed Non-Electric GI Biopsy Forceps are substantially equivalent to the new and unused predicate devices, and will continue to be safe and effective for the maximum number of intended uses.



Surgical Instrument Service & Sterilization

Standards

MediSISS Reprocessed Non-Electric GI Biopsy Forceps are either tested and/or processed in conformance with the applicable parts of the following standards:

- ANSI/AAMI/ISO 11737-1-1995: *Sterilization of Medical Devices—Microbiological Methods—Part 1: Estimation of population of microorganisms on products.*
- AAMI TIR No. 12-1994—*Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.*
- ASTM D4164: 2001 DC 13, AL 1: *Performance Testing of Shipping Containers and Systems.*
- ISO 11607: 2003—*Packaging for terminally sterilized medical devices.*
- ANSI/AAMI/ISO 11135:1994, *Medical devices—Validation and routine control of ethylene oxide sterilization.*
- ANSI/AAMI/ISO 10993:1995, *Biological Evaluation—Part 7: Ethylene Oxide Sterilization Residuals.*
- ASTM F88—*Seal strength of Flexible Barrier Materials.*
- ASTM F1980: 2002—*Standard Guide for Accelerated Aging of Sterile Medical Device Packages*
- United States Pharmacopeia 24—*Sterility Test*
- ASTM F2096-02 *Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test).*

Intended Use

MediSISS Reprocessed Non-electric GI Biopsy Forceps are to be used during minimally invasive endoscopic procedures to remove polyps and obtain tissue samples for microscopic examination.

Contraindications

The MediSISS Reprocessed Non-electric GI Biopsy Forceps should not be used when GI endoscopic procedures are contraindicated.

Conclusion

MediSISS Reprocessed Non-electric GI Biopsy Forceps are substantially equivalent to the legally marketed predicate devices with respect to cleanliness, sterility, design, packaging and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Brandi James
Regulatory Specialist
MediSISS
2747 SW 6th Street
REDMOND OR 97756

FEB 14 2005

Re: K042659

Trade/Device Name: MediSISS Reprocessed Non-Electrical GI Biopsy Forceps
(SEE ENCLOSURE)

Regulation Number: 21 CFR §876.1075

Regulation Name: Gastroenterology-urology biopsy instrument

Regulatory Class: I

Product Code: 78 NON

Dated: December 23, 2004

Received: December 27, 2004

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

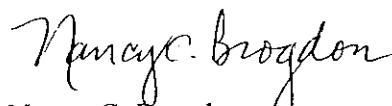
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

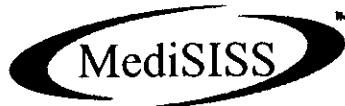
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Surgical Instrument Service & Sterilization

Cover Letter for 510(k) Premarket Notification—
MediSISS Reprocessed Non-Electric Biopsy
Forceps

INDICATIONS FOR USE

510(k) Number (if known): K042659 Ut.v.

Device Name: MediSISS Reprocessed Non-electric GI Biopsy Forceps

Indications for Use:

The MediSISS Reprocessed Non-electric Biopsy Forceps are intended to be used to remove polyps, and obtain a specimen of tissue for microscopic examination.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____
(Optional Format 1-2-96)

(Division Sign-Off)

David A. Lippman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042659

510(k) K042659: MediSISS Reprocessed Non-Electric (“Cold”) GI Biopsy Forceps

The following models (and only the following models, with the descriptions below), which are the subjects of this application, have been found substantially equivalent to the predicate devices listed in K042659.

<u>OEM Model</u>	<u>Description</u>	<u>Jaw O.D.</u>	<u>Length</u>	<u>Sheath Color</u>
Bard 385	Precisor* EXL Coated Biopsy Forceps, Alligator Cup	2.3 mm	230 cm	Blue
Microvasive 1537	Radial Jaw 3 Biopsy Forcep with Needle	2.2 mm	240 cm	Orange
Microvasive 1597	Radial Jaw, 3 Large Capacity Biopsy Forcep with Needle	2.2 mm	160 cm	Yellow
Microvasive 1599	Radial Jaw 3, Large Capacity Biopsy Forcep with Needle	2.2 mm	240 cm	Orange
Olympus FB-240U	EndoJaw, Biopsy Forcep, Oval Cup, Fenestrated with Needle	2.2 mm	230 cm	Blue
Wilson-Cook SDF-2.5-230	Shark Biopsy Forceps, Fenestrated without Spike (Red Handle)	2.5 mm	230 cm	Grey